REMARKS

Original claims 1-14 and 44 and new claim 45-70 are pending in this application for the Examiner's review and consideration. Claims 15-43 are canceled. Applicants reserve the right to file one or more divisional applications directed to the subject matter of the canceled claims or other unclaimed subject matter. Applicants appreciate the Examiner's recognition of patentable subject matter in claims 14 and 44 subject to the double-patenting rejection, discussed below.

Claim 1 was amended to include the feature that the composition is "for oral administration or an injectable composition." Support for administration by injection can be found in the specification at ¶¶ [0033] - [0034] and support for oral administration can be found at in the specification at ¶¶ [0034] - [0035]. Claim 6 was amended to more clearly recite "an ionized form of a C_{10}-C_{22} saturated or un-saturated fatty acid" (*See*, Specification at ¶ [0009]). Claims 13 and 14 were similarly amended to include the recitation of "an ionized form of" linoleic acid and decanoic acid , respectively (*See*, Specification at ¶¶ [0009] and [0011]). Claim 11 was amended to delete the solvent "glycerin" from the Markush group of solvents.

New claim 45 depends from claim 1 and recites the feature that the "composition is for oral administration." New claims 46-57 are of the same scope as claims 3-14 but depend directly or indirectly from claim 45, directed to a composition for oral administration, rather than claim 2, which is directed to an injectable composition. Similarly, new claims 58-70 are of the same scope as claims 3-14 but depend directly or indirectly from claim 44.

No new matter has been added by these claim amendments and new claims so their entry at this time is warranted.

THE REJECTIONS UNDER 35 U.S.C. § 103(A)

The Rejection of Claim 1 as Being Obvious Over U.S. Patent No. 5,719,197 to Kanios *et al.*

Claim 1 was rejected under 35 U.S.C. § 103(a) as being obvious over U.S. patent no. 5,719,197 to Kanios *et al.* ("Kanios") for the reasons set forth on pages 3-4 of the Office Action. Specifically, the Examiner alleges that Kanios discloses a composition comprising a solvent, an active agent, and a carrier and that the solvents include fatty acids such as linoleic acid,

fluoxetine, and 2-hexyl decanoic acid. Therefore, the Examiner alleges it would have been obvious to employ fluoxetine, decanoic acid, and linoleic acid in a composition.

As the Examiner is aware the proper inquiry for obviousness is whether the reference discloses each and every feature of the claim (*See*, MPEP, ¶ 1242) and whether the references suggest the invention and provides one of ordinary skill in the art with a reasonable expectation of success. *In re Vacek*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991); *In re O'Farrell* 853 F.2d 894, 7 U.S.P.Q. 2d 1673 (Fed. Cir. 1988).

Kanios does not disclose each and every feature of the invention recited in claim 1, as amended, suggest the invention, or provide a reasonable expectation of success. Without limitation as to other deficiencies in Kanios, that references does not, at a minimum, disclose or suggest a composition that is "for oral administration or an injectable composition." Rather, Kanios discloses compositions that are for topical administration. The compositions disclosed in Kanios are not described as being suitable for oral administration or administration by injection. The requirements for a composition for topical administration are completely different from those for a composition for oral administration or administration by injection. For example, compositions for topical administration, unlike compositions for oral administration or administration by injection, must be able to adhere to the skin or mucosa (*See*, Kanios, column 4, lines 62 to column 5, lines 5 and column 6, lines 23-27). Indeed, the compositions disclosed in Kanios include excipients, such as clays and bioadhesives, which allow the compositions to adhere to the skin and mucosa, that would not be suitable for inclusion in a composition for oral administration or administration by injection. Formulations for oral administration must be adequately absorbed when ingested and injectable formulations must be taken up into the system without causing undue tissue damage. Kanios is silent regarding these differences. There is simply no disclosure or suggestion in Kanios of a composition for oral administration or administration by injection or that the topical compositions disclosed therein could be modified so as to be suitable for oral administration or administration by injection. Moreover, even if Kanios did suggest that the formulations disclosed therein could be formulated for oral administration or administration by injection, which it does not, the reference does not provide the requisite reasonable expectation that such a composition, if formulated for oral administration or administration by injection, would successfully release the active compound

over time. Indeed, the Examiner recognized that dependent claim 2, directed to an injectable composition, is patentable over Kanios. Accordingly, Applicants respectfully submit that Kanios does not render claim 1, as amended, obvious.

For the reasons set forth above, Applicants respectfully request that the rejection of claim 1 under 35 U.S.C. § 103(a) as being obvious over Kanios has been overcome. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

The Rejection of Claims 1-13 as Being Obvious Over U.S. Patent No. 5,574,020 to Klink *et al.*

Claims 1-13 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. patent no. 5,574,020 to Klink *et al.* ("Klink") in view of Remington's Pharmaceutical Science (1975) 15th ed. pages 181-182 ("Remington's") for the reasons set forth on pages 4-5 of the Office Action. Specifically, the Examiner alleges that Klink discloses a formulation comprising an antibiotic, a pharmaceutically acceptable solvent, and that phosphoric acid can be added to the formulation. The Examiner then asserts that acids other than phosphoric acid, such as lauric acid, can be used in the formulation. The Examiner acknowledges that Klink does not disclose that the composition disclosed therein precipitates when injected into water, an aqueous solution, or a mammal and releases the drug over a period of time. The Examiner, however, goes on to assert that Remington's teaches that hydrophobic bonding is important for stabilizing protein structure, drug-protein binding, transport and storage of drugs, and drug receptor interactions. Therefore, the Examiner asserts it would have been obvious to employ a hydrophobic solvent that will precipitate when introduced into an aqueous solvent.

Klink, like Kanios, also does not disclose each and every feature of the invention recited in independent claim 1, as amended, suggest the invention, or provide a reasonable expectation of success. Specifically, Klink does not disclose or suggest a composition that includes a water immiscible solvent, as recited in independent claim 1. Rather, Klink discloses an aqueous composition that includes tilmicosin and propylene glycol that has a pH adjusted to about 6 (*See*, Klink, column 1, lines 36-46). Propylene glycol, however, is a water miscible solvent, not a water immiscible solvent. Moreover, there is absolutely no disclosure or suggestion in Klink to replace the water miscible solvent propylene glycol with a water immiscible solvent or, for that

matter, to replace the propylene glycol with any other solvent.

Remington's does not remedy the deficiencies in Klink. Remington's simply provides a discussion of the various types of intermolecular binding forces that occur in nature. There is, however, absolutely no disclosure or suggestion in Remington's to replace a water miscible solvent in a pharmaceutical formulation, such as the formulation disclosed in Klink, with a water immiscible solvent. Indeed, Remington's does not provide any basis for or provide an advantage that would be obtained by making such a replacement. Moreover, neither Klink nor Remington's, either alone or in combination, provides the requisite reasonable expectation of success. Neither Klink nor Remington's provides any expectation that a composition comprising the salt of a pharmacologically active compound and a lipophilic counterion and a water immiscible solvent, as claimed, would successfully provide a composition that releases the active compound over time.

Furthermore, Applicants note that the composition disclosed in Klink would not be suitable for injection, as required in claims 2-14, if the phosphoric acid is replaced with a fatty acid (*i.e.*, a lipophilic counterion), as alleged by the Examiner. Applicants attach hereto, as Exhibit A, a Declaration by Yerramilli V.S.N. Murthy, one of the inventors, ("Declaration") that was submitted in application serial no. 10/264,445 showing that the composition disclosed in Klink would not be suitable for injection if the phosphoric acid is replaced with a fatty acid. The Declaration shows that, although Klink alleges that other acids (including lauric acid) may be used to adjust the pH of the tilmicosin/water slurry used to prepare the formulation disclosed therein, there is no evidence in Klink that any of these acids can replace phosphoric acid for generating injectable tilmicosin formulations. Specifically, Dr. Murthy prepared several formulations according to the disclosure of Klink using various acids to adjust the pH. In particular, when the fatty acids lauric acid, palmitic acid, pamoic acid, or stearic acid (*i.e.*, lipophilic counterions) were used to make the formulation, the resulting composition was a highly viscous precipitate that was too viscous to be drawn into a syringe and, therefore, was not an "injectable composition," as recited in dependent claims 2-14 (*See*, Declaration ¶ 77-16 and Figures C, D, E, F, and G). Accordingly, Klink fails to disclose or suggest a composition that comprises the salt of a pharmacologically active compound and a lipophilic counterion that is "injectable," much less a composition that comprises a water immiscible solvent. Accordingly,

Applicants respectfully submit that the combination of Klink and Remington's does not render claims 1-13, as amended, obvious.

For the reasons set forth above, Applicants respectfully request that the rejection of claims 1-13 under 35 U.S.C. § 103(a) as being obvious over the combination of Klink and Remington's has been overcome. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

DOUBLE PATENTING

Claims 1-14 and 44 were rejected on the grounds of non-statutory obviousness-type double patenting as being unpatentable over claims 1-63 of U.S. patent no. 6,887,487 to Murthy *et al.* ("Murthy") for the reasons set forth on pages 5-6 of the Office Action. Specifically, the Examiner alleges that claims of the present application are not patentably distinct from the claims of Murthy because the present application and Murthy recite substantially the same subject matter differing only in the description of the particular components claimed.

In response to the Examiner's assertion that claims 1-14 and 44 are rendered unpatentable for non-statutory obviousness-type double patenting over Murthy, Applicants submit herewith a Terminal Disclaimer disclaiming the term of any patent that should issue from the above-identified application that would extend beyond the term of Murthy.

For the reasons set forth above, Applicants respectfully submit that the rejection of claims 1-14 and 44 as being unpatentable for non-statutory obviousness-type double patenting has been overcome. Accordingly, Applicants respectfully request that the rejection of these claims for non-statutory obviousness-type double patenting be reconsidered and withdrawn.

ALLOWED CLAIMS

Applicants appreciate the Examiner's recognition that the subject matter of claims 14 and 44 is patentable, subject to the filing of a Terminal Disclaimer. As discussed above, Applicants have filed a Terminal Disclaimer disclaiming the term of any patent that should issue from the above-identified application that would extend beyond the term of Murthy. Accordingly, claims 14 and 44 should be allowed. New claims 58-70, which depend from claim 44, should also be

allowed.

CONCLUSIONS

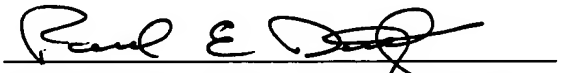
It is respectfully submitted that all claims are now in condition for allowance, early notice of which would be appreciated. Should the Examiner disagree, Applicants respectfully request a telephonic or in-person interview with the undersigned attorney to discuss any remaining issues and to expedite eventual allowance of the claims.

A Petition for Extension of Time to extend the time for responding by one (1) month from September 29, 2006 to and including October 30, 2006 (because October 29, 2006 is a Sunday) with provision for the applicable fee is also submitted herewith.

No fee is believed to be due for this submission. Should any additional fees be required, please charge the required fees to Kenyon & Kenyon deposit account no. 11-0600.

Respectfully submitted,

Date: October 6, 2006



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